Med-Sonics

MAR 30 2012

SECTION - 5

510(k) Summary

per 21 CFR 807.92

UreTron™ Multi Probe Lithotripter

510K #: K111058

SPONSOR

MED-SONICS, CORP.
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Erie, Pennsylvania 16509 USA
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Contact Person: William A. Stoll
Date Prepared: April 15, 2011

DEVICE NAME

Trade/Proprietary Name: **UreTron Multi Probe Lithotripter**
Common/Usual Name: Intracorporeal ultrasonic lithotripter
Classification Name: Lithotripter, Ultrasonic [21 CFR 876.4480]
Product Code: FFK
Class: II

PREDICATE DEVICES

510K Number: K102169
Manufacturer: Cybersonics, Inc.
Trade Name: CyberWand Hollow Semi-Flexible Ureteral Probe Lithotripter

510K Number: K052135
Manufacturer: Cybersonics, Inc.
Trade Name: CyberWand Dual Probe Lithotripter

510K Number: K012445
Manufacturer: Electro Medical Systems SA.
Trade Name: EMS Swiss Lithoclast Master / Swiss Lithoclast Ultra

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DEVICE DESCRIPTION

The UreTron Multi Probe Lithotripter system is intended to be used for the fragmentation and removal of urinary tract calculi in the kidney, ureter and bladder. The system is an electromechanical device and consists of a generator, hand piece and probes. The hand piece is an ultrasonic transducer containing piezo-electric ceramic elements. The generator drives the hand piece at 21000 +/- 1000 Hz to get mechanical vibration through the probes to urinary tract calculi.

INTENDED USE

The UreTron Multi Probe Lithotripter system is intended to be used for the fragmentation and removal of urinary tract calculi in the kidney, ureter and bladder.

BASIS FOR SUBSTANTIAL EQUIVALENCE

Med-Sonics UreTron Multi Probe Lithotripter system is substantially equivalent to the CyberWand Hollow Semi-Flexible Ureteral Probe Lithotripter (K102169), the CyberWand Dual Probe Lithotripter (K052135) and EMS Swiss Lithoclast Master/Ultra (K012445), which were previously cleared for the fragmentation and removal of urinary tract calculi in the kidney, ureter and bladder. The UreTron has the same intended use and similar technical specifications as compared with predicate devices.

PERFORMANCE DATA

The UreTron was tested by NRTL labs for EMC and Electrical Safety according to IEC 60601. Verification and Validation tests were conducted to demonstrate the UreTron's functionality, sterility and biocompatibility for its intended use. These verification and validation test results substantiated safety and effectiveness compared to the predicate devices.

Substantial equivalence with predicate devices is demonstrated by stone model fragmentation testing, probe life testing and tissue perforation testing. The test data proves UreTron's efficacy with stone model penetration rates as compared to the predicate devices.

CONCLUSION

Med-Sonics' UreTron Multi Probe Lithotripter system is substantially equivalent to the legally marketed devices compared herein.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 30 2012

Mr. William A. Stoll
VP Quality & Regulatory
Med-Sonics Corp.
4960 Pittsburgh Ave, Suite A
ERIE PA 16509

Re: K111058
Trade/Device Name: UreTron Multi Probe Lithotripter
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic lithotriptor
Regulatory Class: II
Product Code: FFK
Dated: March 2, 2012
Received: March 5, 2012

Dear Mr. Stoll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION - 4

Indications for Use

510(k) Number (if known): **K111058**

Device Name: **UreTron Multi Probe Lithotripter**

Indications for Use:

The UreTron Multi Probe Lithotripter system is intended to be used for the fragmentation and removal of urinary tract calculi in the kidney, ureter and bladder.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

3/30/2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111058